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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,649	09/04/2003	Yougandh Chitre	A03P1061	8324

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,649	CHITRE ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communicat on, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 04 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/4/03, 5/17/04. 3/17/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 10 of copending Application No. 11/376,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a preformed region adjacent the distal end of a cardiac lead to provide passive fixation is old and well known in the cardiac lead manufacturing arts. Preformed regions such as tines or pre-shaped lead body anchors have long been used to fix the lead to the heart. The examiner takes Official Notice to this effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 5, 7, 8, 10-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (Pat. No. 5,899,929).

Note in particular the text abridging cols. 7 and 8, as well as col. 7, lines 1-9 and Figs. 1B and 4C.

Particularly concerning claims 5 and 14, the examiner considers the helix of Thompson et al. to be extendable into the cardiac tissue.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 3, 6, 15 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. in view of Helland et al. (Pat. No. 5,545,201).

Regarding claim 2, Thompson et al. do not discuss the use of a helical tip electrode. Helland et al., however, disclose a cardiac lead wherein the active fixation helix is utilized as an electrode to provide bipolar pacing. Those of ordinary skill in the art would have readily recognized the use of a helical electrode to constitute a matter of obvious design. Such configurations are old and commonplace in the art when one desires to ensure good contact with the cardiac tissue. To utilize the fixation helix shown in Fig. 1B of Thompson et al. as an electrode in order to take advantage of the

improved electrode/tissue interface contact would have therefore been considered blatantly obvious to anyone of ordinary skill. Related comments apply to claim 18.

Regarding claim 3, the examiner takes Official Notice that it is old and well known in the cardiac lead arts to incorporate extendable/retractable helical tips in order to allow for precise anchoring when implanting the lead. The extendable/retractable tip further lessens the chance for tissue damage upon progression of the lead in the vasculature.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al.

Regarding claim 9, although Thompson et al. are silent as to the exact spacing between a distal extremity of the lead and the defibrillation electrode, the applicants give no criticality to such spacing. Clearly the spacing depends upon the particular location of the lead within the heart and the various dimensions of the heart itself. Any distance along the lead allowing for effective electrode placement and efficient defibrillation would have been seen as an obvious matter of design to those of ordinary skill in the art looking to best treat the patient.

8. Claims 1-6, 8-15, 17-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as obvious over Helland (Pat. No. 7,027,852).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Regarding claim 1, Helland discloses an implantable medical device comprising a lead body 12 with a connector assembly 24 and a tip electrode (for the sake of illustration, the electrically active helix 294 of Fig. 18), as well as a second electrode (for the sake of illustration, ring electrode 292) having a surface area in the range of 14 to 40 mm^2, and the tip electrode having an area in the range of 3.0 to 10 mm^2 (see col. 8, lines 50-55). Although Helland does not explicitly discuss the spacing between the second electrode and the tip electrode, given the fact that both leads are attempting to reduce the effects of far-field noise, the fact that both leads are configured and sized for implant within the same regions of the heart, the fact that both leads are used for pacing and thus carry electrodes of similar dimensions, the fact that the conductive portion of the helix in the '852 patent may include either the mid-section or an exposed distal tip (see col. 9, lines 17-23) thus allowing for a range of spacings between the second electrode and the tip electrode, and the fact that the patent suggests that the inter-electrode spacings may range up to about 0.4 mm in the embodiment shown in Figs. 6 and 7 (see col. 8, lines 5-19) thus forcing the lead diameter to be of a size greater than 0.4 mm and the helix to be correspondingly relatively sized a sufficient length to mechanically hold the lead in proper position, those of ordinary skill in the art would have seen the spacing range of 1.0 mm to about 3.5 mm to fall within the range of spacings one would necessarily be limited to by virtue of the above stated facts. Furthermore, the exact spacing would depend upon routine clinical experimentation to best determine the most appropriate spacing to limit the effects of far-field noise –a common goal between both the patent and application. Those of ordinary skill in the art would have therefore considered the recited 1.0 to 3.0 mm spacing to be a matter of obvious design. Related comments apply to similarly worded claims 13 and 18.

Regarding claim 3, Helland discloses that the helix is connected to a rotatable pin on the connector assembly (col. 8, lines 46-55). The examiner takes Official Notice that such structure is widely known by those of ordinary skill in the art to enable extension and retraction of the helix upon implant. The examiner also points to par. 00043 of the

present specification which concurs by stating that such fixation mechanisms are old and well-known in the art.

Regarding claim 8, Helland discloses that the lead may include cardioverting-defibrillating electrodes (col. 3, lines 4-8). To dispose this type of electrode on the distal end of the lead proximal to the second electrode would have been considered blatantly obvious to those of ordinary skill in the art since such a location would place the electrode at the proper position to maximize defibrillation effectiveness and is old and well-known in the art.

Regarding claim 9, although Helland is silent as to the exact spacing between a distal extremity of the lead and the defibrillation electrode, the applicants give no criticality to such spacing. Clearly the spacing depends upon the particular location of the lead within the heart and the size of the heart itself. Any distance along the lead allowing for effective electrode placement and efficient defibrillation would have been seen as an obvious matter of design to those of ordinary skill in the art looking to best treat the patient.

Concerning claim 12, as the applicant states in par. 00043 of the present specification, passive and active fixation mechanisms are well known by skilled artisans. The decision as to which system to use has been considered a classic matter of design in the cardiac lead arts, with the decision depending upon a large number of application and manufacturing dependent parameters. Clearly any means sufficient to fix the distal tip of the lead to the heart would have been within the realm of the Helland patent.

9. Claims 7, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland as applied to claims above, and further in view of Berthelsen (Pat. No. 4,953,564).

Helland does not discuss the use of a steroid disposed on the distal region of the lead. Berthelsen, however, discloses a cardiac lead wherein a steroid is indeed located at the distal end of the lead. As is old and well known in the medical arts and taught by Berthelsen, the use of such a drug acts as an anti-inflammatory agent, reducing the adverse reaction of the tissue to the stimulation electrode. Those of ordinary skill in the cardiac treatment arts desiring to take advantage of such a benefit,

would have therefore seen the obviousness of disposing a steroid at the distal end of the Helland lead.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 16, 2006

KENNEDY SCHAETZLE
PRIMARY EXAMINER